Section 4: 510(k) Summary

Date of Summary Preparation: February 5, 2009

FEB - 9 2009

Contact: Michael Treas
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Product	Product Code	Regulation and Classification Name
Compex® Sport Plus	NGX	Powered Muscle Stimulator/ Powered Muscle Stimulator for Muscle Conditioning (21 CFR 890.5850)

Predicate Device: Compex® Sport (K011880)
Globus Premium Sport and fitness Muscle Stimulators (K061632)

Indications for Use:
The Compex® Sport Plus is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.

The Compex® Sport Plus is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Compex® Sport Plus training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated.

The Compex® Sport Plus electrical impulses allow the triggering of action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.

The various types of muscle work that the Compex® Sport Plus can impose on the stimulated muscles are able to improve or facilitate muscle performance.

The Compex® Sport Plus may therefore be considered a technique of muscle training.

Product Description:
The Compex® Sport Plus system consists of these components:

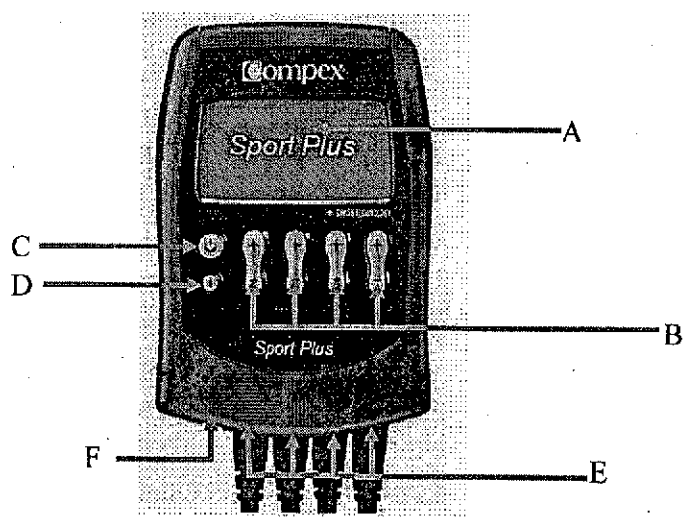
- 1x Stimulator
- 1x Wire Set

- 2x Small Performance Snap Electrode package
- 2x Large Performance Snap Electrode package
- 1x Fast Charger

These components are packaged together in a carrying case along with the user manual, belt clip and a battery charger.

The stimulator is a microprocessor controlled 4 channels neuro-muscular electro-stimulator. The stimulator drives each output channel independently based upon the parameters pre-defined for a program selected by the user. The user operates the device through a User Interface (UI) consisting of a graphic LCD, keypad controls and supporting software. The User Interface is made up of different menus that allow the following functions: set up the device (Options Menu), select a desired category (Category Menu), select a preset program (Treatments´ Menu), tune a selected program (Stimulation Menu), and adjust the stimulation intensities (Level Menu).

Figure 1 Stimulator



A. LCD Display
B. "+/-" buttons of the 4 stimulation channels (used as adjustment, selection or confirmation buttons)
C. "ON/OFF" button (can also be used as "Back" button)
D. *i*-button
E. Four sockets for the 4 Lead Wires
F. One socket for the battery charger

The stimulator is housed in a molded portable plastic case with a viewable LCD display, an accessible keypad, and accessible battery storage compartment. The case shape is rectangular.

The LCD is located on the upper half of the rectangular face of the device, above the keypad. The display is a graphic display capable of showing alpha numeric characters (including lower case characters), most standard ASCII symbols, and graphics appropriate to assist the user in selecting a desirable exercise routine. The LCD is used to display system information to the user.

The device is equipped with a keypad composed of push buttons which is located below the LCD. The function is defined by a symbol on the LCD corresponding to the button below.

Power for the device is provided from a 4.6 Volt rechargeable Ni-MH battery pack. The power source is housed behind an operator access panel on the back of the device cover.

Each lead wire will connect the output of the stimulator to the electrodes for each output channel. Each lead wire will be connected to the stimulator using a high friction, forced fitting, mechanically shielded connector. Electrode connection shall be a mechanically shielded snap connector (Compliant with protected lead wire and patient cable safety requirements).

Electrode configurations are made up of existing electrode types. Electrodes are configured for the intended use applications and may be unique to one or more application. Up to four Active/Passive sets of electrodes are required. Each electrode set requires a lead/connector assembly. The electrode connector shall be compatible with the cable connector. The electrode assembly shall be compliant with regulatory requirements.

The electrodes (non sterile electrodes) are applied parts which conform to the BF classification of the IEC60601-1 standard and the particular safety standard for nerves and muscles stimulators: IEC60601-2-10.

It is not possible to connect the stimulator to the charger at the same time as the lead wires. Connecting a charger to the stimulator results in an automatic start of the charging procedure which is indicated by a symbol on the LCD showing the status of the battery pack. The battery pack of the stimulator shall be charged by a switching adapter able to supply an output current of 1.4 A +/-100 mA and an output voltage of 9 VDC +/- 2%. The primary plug shall be of American 2 pin AC type able to handle input voltage from 90 to 240 VAC and at a maximum input current of 0.5 A. The secondary plug, to be attached to the stimulator, shall be a straight jack plug with the following dimensions, outer diameter: 3.5 mm, inner diameter: 1.3 mm and length: 9 mm. The charger shall have short circuit protection. Maximum dimensions of the charger shall be 72 x 52 x 35 mm.

Program Descriptions:

Training Programs

Compex® Sport Plus provides four stimulation training programs. They correspond to the type of muscle performance the sportsman wishes to improve or maintain. Their claims are clearly restricted to the stimulated muscles.

Each of these four training programs offers five different working levels that enable the amount of work to be gradually increased.

"Endurance" program

The Endurance program imposes on the stimulated muscle a pattern of activities resembling the one that is delivered by the nerve to slow fibers during voluntary endurance exercises. It develops the aerobic metabolism of the stimulated fibers and their capillary supply. It improves resistance to fatigue for long duration exercises of average medium working power level.

"Resistance" program

The Resistance program imposes on the stimulated muscle a pattern of activities resembling the one that is delivered by the nerve to fast fibers during voluntary heavy resistances exercises. It develops the

glycolysis metabolism of the stimulated fibers and their capillary supply. It improves resistance to fatigue for short duration exercises of average high working power level.

"Strength" program
The Strength program imposes on the stimulated muscle a pattern of activities resembling the one that is delivered by the nerve to fast fibers during voluntary strength exercises. It develops the cross-sectional area of the stimulated fibers. It improves the maximum strength of isometric and dynamic contractions.

"Explosive Strength" program
The Explosive Strength program imposes on the stimulated muscle a pattern of activities resembling the one that is delivered by the nerve to fast fibers during voluntary rapid strength development exercises (ballistic movement). It develops the strength and/or the contraction speed of the stimulated fibers. It improves the explosive strength.

Other programs
Compex® Sport Plus offers five other programs that are not intended to train muscles. Their objective is to prepare muscle for explosive motion or other training or to facilitate recovery after active muscle training or competition.

"Potentiation" program
The Potentiation program produces the physiological muscle phenomenon known as "Twitch potentiation". A muscle with potentiated fibers has more velocity and reaches its maximum strength more easily and rapidly.

"Active Recovery" program
The Active Recovery program produces muscle twitches at a very low frequency. Those twitches act like a massage and induce an increase of the blood flow and a faster reduction of the lactic acid blood level. It facilitates recovery of the stimulated muscles after active muscle training or competition.

"Recovery Plus" program
The Compex Recover Plus program is a sub-set of the Active Recovery program that produces a very low constant frequency to induce a gentle muscle contraction and vibration to increase in blood flow. This program should be used after training sessions and competitions.

"Pre-Warmup" program
The Compex Pre-Warmup program helps muscles to get ready and should be used before training sessions and before competitions.

"Massage" program
The Compex Massage program produces gentle muscle twitches, like a massage, to facilitate recovery from muscle fatigue and to help recover muscle strength after training sessions and competitions.

Substantial Equivalence: When compared to the predicated device, Compex® Sport (011880) and Globus Premium Sport and fitness Muscle Stimulators (K061632), the Compex® Sport Plus has the same intended use. Therefore, Compex® Sport Plus is substantially equivalent to the predicate marketed device, Compex® Sport (K011880) and Globus Premium Sport and fitness Muscle Stimulators (K061632)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

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% Mr. Michael Treas
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FEB - 9 2009

Re: K083140
Trade Name: Compex® Sport Plus
Regulation Number: 21 CFR 890.5850
Regulation Names: Powered muscle stimulator
Regulatory Class: II
Product Code: NGX
Dated: January 19, 2009
Received: January 21, 2009

Dear Mr. Treas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Device Name: Compex® Sport Plus

510(k) Number if known:_____

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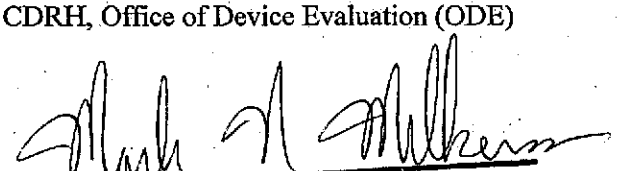
Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083140